



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** 3/24/2020

**SUBJECT:** Efficacy Review for NP 4.5 (D&F) Detergent/Disinfectant  
EPA Reg. No. 1839-95,  
DP Barcode #456932  
E-submission #47896

**FROM:** Sophie Nguyen  
Efficacy Evaluation Team  
Antimicrobials Division (7510P)  
Date Signed: 3/23/2020

**TO:** Eric Miederhoff, PM 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**APPLICANT:** Stepan Company  
22 W. Frontage Rd.  
Northfield, IL 60093

**FORMULATION FROM LABEL:**

<u>Active Ingredient</u>	<u>% by wt.</u>
Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chloride.....	2.25%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride.....	2.25%
<u>Other Ingredients</u> .....	<u>95.50%</u>
Total .....	100.00%

## **I. BACKGROUND**

**Product Description (as packaged and applied):** Liquid Concentrate

**Submission Type:** Label Amendment

**Requested Action:** To add emerging viral pathogen claim language to the master label in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*.

**Documents Submitted for Consideration:**

- Cover letter to EPA (dated March 12, 2020),
- Data Matrix (dated May 13, 2019)
- Proposed product label (dated March 12, 2020)
- Terms of Registration Letter (dated March 12 and March 18, 2020)

## II. CONCLUSION

MRID (year)	Emerging virus claim	Organism(s)	Type of Virus	Surface Type	Application Method(s) and/or Dilution	Contact Time Tested	Soil Load	Study(ies) support listed virus(es)
46454601 (2004), Cited from *Reg.#1839-81 (Review dated 4/28/2004)	Enveloped Virus & Large Non-Enveloped Virus	Feline calicivirus, University of Ottawa (surrogate for Norovirus) (Caliciviridae)	Small non- enveloped virus	Hard non- porous surface	1:128 (1 oz/gal) using <b>deionized water</b>	10 min.	5% soil	Yes
46454602 (2004), Cited from *Reg.#1839-81 (Review dated 4/28/2004)	Enveloped Virus & Large Non-Enveloped Virus	Feline calicivirus, University of Ottawa (Caliciviridae)	Small non- enveloped virus	Hard non- porous surface	1:128 (1 oz./gallon) using <b>deionized water</b>	10 min.	5% soil	Yes

\* EPA Reg. #1839-81, NP 9.0 Detergent/Disinfectant, total Quat nominal concentration at 9.0%.

### III. LABEL COMMENTS (label dated 3/12/20)

1. The proposed label claims that the product, NP 4.5 (D&F) Detergent/Disinfectant (EPA Reg. No. 1839-95), qualifies for the following emerging viral pathogens claims as indicated on the Terms of Registration Letter dated March 12, 2020:

<i>For an emerging viral pathogen that is a/an...</i>	<i>...following the directions for use for the following organisms on the label:</i>
Enveloped virus	Norovirus

This claim is **acceptable** as it is supported by the cited data.

2. Please make the following changes to the proposed label:
  - a. In the Directions for Use and Marketing Claim sections, when instructing users to dilute the product for use against the Emerging Viral Pathogen claim above, the water recommended for use should be deionized water. Efficacy data for Norovirus showed effectiveness of product when diluted in deionized water; the label claim should reflect this water diluent condition.
  - b. On page 2, remove “*This claim can only be used if product is currently in the EPA L list: Product (Product name) can be found on EPA list L: ‘Registered antimicrobial products that meet CDC criteria for use against the EBOLA virus...*” EPA Lists are not for marketing purposes on antimicrobial product labels.
  - c. On page 7, if stability data had been submitted to substantiate the stability time frame of the use-solution, please specify the stability time frame reflective of submitted data. How would users determine which is the appropriate stability time frame to follow?
  - d. On page 8, remove the following health conditions:
    - i. Causative agent of fever blisters,
    - ii. Causative agent of upper respiratory infections,
    - iii. Representative of the Pox virus group,
    - iv. Causative agent of Infectious Canine Hepatitis,
    - v. Causative agent of Canine Coronavirus Disease,
    - vi. Canine Gastroenteritis,
    - vii. Causative agent of viral Kennel Cough,
    - viii. Causative agent of Feline Herpes Virus Infection,
    - ix. Feline Infectious Peritonitis

Claims of infections and diseases are not allowed on antimicrobial product labels.

- e. On page 8, remove the statements concerning product effectiveness against all Influenza A viruses. The Emerging Viral Pathogen claim supersedes the Pandemic 2009 H1N1 Influenza A virus policy. Registrant should submit efficacy data to

substantiate effectiveness against specific Influenza viruses.

- f. Under Marketing Claims, when one-step claims are being made with cleaner and disinfection (e.g., “one-step disinfectant cleaner”), please add the qualifier “when the Use-Directions for disinfection are followed”.
- g. On page 11, under Water and Smoke Damage Restoration against Odor-Causing Bacteria and Fungi, please remove “for institutional” and “hospital use”. Non-public health uses cannot be marketed for healthcare and hospital use.